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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/820,339 | 03/29/2001 | Sara Fuchs | FUCHS=2A | 3100 |

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| EXAMINER | |
|---|---|
| HAYES, ROBERT CLINTON | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1649 | |

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/820,339 | FUCHS ET AL. | |
| | Examiner | Art Unit | |
| | Robert C. Hayes, Ph.D. | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *8,9,12,14-18,25,27,30,31 and 36-41* is/are pending in the application.

4a) Of the above claim(s) ___ is/are withdrawn from consideration.

5)☒ Claim(s) *12* is/are allowed.

6)☒ Claim(s) *8,9,15-18,30,31 and 36-39* is/are rejected.

7)☒ Claim(s) *14,25,27,40 and 41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/06/06 has been entered.

2. Applicants' arguments filed 2/06/05 have been considered but are not found persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The objection to claims 25, 27, 28, 32, 36 & 40 because of misspelling "toler*a*gen" is withdrawn due to the amendment or cancellation of the claims.

5. The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the cancellation of this claim.

6. The rejection of claims 8, 16-19, 30 & 36-39 under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete is withdrawn due to the amendment or cancellation of the claims.

7. The rejection of claims 8, 9, 16-18, 30 & 36-39 under 35 U.S.C. 102(b) as being anticipated by Schoepfer et al. (1988), is withdrawn solely because of the "proviso" now recited in claim 8. Note that this rejection will likely be re-instated should Applicants obviate the new matter rejection below.

8. Claim 12 is allowed.

9. Claims 14, 25, 27 & 40-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

It is again suggested that claim 32 (iii) be amended to " a polypeptide Hα1-210 consisting of **the** amino acid residues of SEQ ID NO: 2" to reflect more conventional claim language.

10. Claims 8, 9, 15-18, 30-31 & 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis not conception in context with that described within the specification at the time of filing the instant application exists for the negative recitation of "with the proviso that said polypeptide tolerogen does not consist of residues 1-210 of SEQ ID NO: 2" after the functional language suggested by the Examiner related to α-bungarotoxin. No such basis exists on page 28 of the specification; thereby, constituting new matter.

11. Claims 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is ambiguous how a "polypeptide tolerogen [that] does not consist of residues 1-210 of SEQ ID NO: 2" can also "consist... of amino acid residues 1-210 of SEQ ID NO: 2" as recited in (c), which is contradictory.

12. Claims 8, 16-18, 30 & 36-39 stand rejected under 35 U.S.C. 102(b) as being anticipated by Talib et al. (1991; IDS Ref #AM), for the reasons made of record in Paper NOs: 11 (mailed 1/30/03), 14 (mailed 10/14/04), 20040721 & 20050603, and as follows.

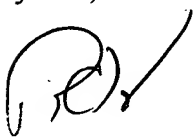
In contrast to Applicants' arguments on pages 11-12 of the response, the recitation of "fused to an additional polypeptide at its N- and/or C-terminal end" to "amino acid residues 122-210 of SEQ ID NO: 2" in claims 8(iv) & 36 are still met by the teachings of Talib et al. (e.g., see page 291). *In arguendo,* the sole difference between Talib's sequence and DNA encoding Hα1-

210 of claims 8(iv), 30 & 36 is the mere addition/fusion of the Met start codon residue at the N-terminal end of SEQ ID NO: 2, as indicated in Figure 1, which therefore, meets the "proviso that said tolerogen does not consist of residues 1-210 of SEQ ID NO: 2". In that this Met start codon is inherently removed during proteolytic processing of eukaryotic proteins, Talib's DNA then "cod[es] for a polypeptide tolerogen ... consisting of amino acid residues [1-210] of SEQ ID NO: 2". This fusion polypeptide of Talib also inherently "does not assume the native conformation of the α subunit of the human acetylcholine receptor" because Talib's polypeptide constitutes a truncated version of the human acetylcholine receptor which is the extracellular domain of this receptor subunit. Note, pages 20 & 26 of the specification disclose that the AChR α-subunit *extracellular* domain polypeptide itself functions as a tolerogen. Note further that it is well known in the art that polypeptides produced in *E.coli*, as taught by Talib, often are not properly folded, and therefore, do "not assume the native conformation of the α-subunit of the human acetylcholine receptor", as recited. Nevertheless, *in arguendo,* because Talib teach a structure identical to that claimed, inherently it reasonably possesses any functional properties associated with that claimed structure. Thus, Applicants' arguments are not persuasive.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
April 18, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER